IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

#1 9(CNE) 1/12/99 T. Gray

Applicants: John B. Harley and Judith A. James

Serial No: 08/781,296 Examiner: M. Zeman

Filing date: January 13, 1997 Art Unit: 1643

For: "*Diagnostics and Therapy of Epstein-Barr Virus in Autoimmune Disorders*"

Assistant Commissioner of Patents
Washington, D.C. 20231

DECLARATION UNDER 37 C.F.R. §1.132 OF DR. JOHN HARLEY

Sir:

I, John B. Harley, hereby declare that:

1. I am an inventor of the subject matter described and claimed in the above-identified patent application.

2. I received my B.S. in Physics and Chemistry from Dickinson College, Carlisle, Pennsylvaia in 1971. I received by Ph.D. in Biochemistry from the University of Pennsylvania, Philadelphia, Pennsylvania, in 1976. I received my M.D. from the Univeristy of Pennsylvania, Philadelphia, Pennsylvania in 1974. I am Board Certified as a Diplomat of the American Board of Internal Medicine, American Board of Rheumatology and the American Board of Allergy and Immunology. I am current the James R. McEldowney Professor of Immunology and Professor of Medicine, Adjunct Professor Department of Microbiology and Adjunct Professor Department of Pathology at the University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma; A Member, Arthritis and Immunology Program, Oklahoma Medical Research Foundation, Oklahoma city, Oklahoma. My Curriculum Vitae is attached.3. We have conducted

additional studies which show an association between Epstein-Barr virus and another autoimmune disorder, inflammatory polyarthritis.

To preliminarily address the issue of association we obtained sera from some of the cases and controls in the Norfolk Arthritis Register. This is an RA disease inception study where all of the available patients in this region of England with inflammatory polyarthritis were enrolled as close to presentation as was possible along with appropriate controls. The overwhelming majority of these cases satisfy the 1987 Classification Criteria for RA. Our collaborator in this effort, Professor Alan Silman, has sent us 174 blinded sera from this resource collected at enrollment interview of patients with polyarthritis, thought to be typical for the presentation of RA, and controls. We assayed these blinded serum specimens for anti-EBV VCA IgG (Epstein-Barr virus Viral Capsid Antigen), anti-CMV IgG (cytomegalovirus), anti-HSV-1 IgG (herpes simplex virus, type 1), and anti-HSV-2 IgG (herpes simplex virus, type 2), using the methods described in our patent application.

Table 1. Preliminary association of anti-EBV VCA IgG with inflammatory polyarthritis with sera from the Norfolk Arthritis Register.

	Anti-EBV-VCA IgG		Anti-CMV IgG		Anti-HSV-1 IgG		Anti-HSV-2 IgG	
	+	-	+	-	+	-	+	-
RA	78	2	30	50	41	39	26	65
Controls	78	13	40	51	46	45	23	57
Odds Ratio	6.5		0.8		1.0		1.0	
Π^2	7.4		0.7		0.0		0.0	
P value	<0.01		NS		NS		NS	

NS=not significant. Analysis is done by the McNemar test.

Upon receipt of the anti-viral assay results in Manchester the code was broken and the analysis is proceeding in both centers. The results show support for association of EBV seropositivity just after presentation with inflammatory polyarthritis.

There is no obvious association of inflammatory arthritis with seropositivity against HSV-1, HSV-2 or CMV. There is however, a strong but not perfect association of anti-EBV IgG with the cases. While significant, these numbers are small and warrant being established in a group of sufficient size to more accurately estimate the odds ration and to explore the RA patients who are seronegative with regard to EBV.

One of the possible artifacts is that something about RA generates false posistives in the anti-EBV VCA IgG assay. The obvious candidate for such nefarious interference is rheumatoid factor (RF). Data in the literature supports there being no interference between the anti-EBV VCA IgG and RF. Nevertheless, we have explored this issue by removing approximately 90% of the RF activity by solid phase absorption with human IgG from four RA patients who were RF seropositive and from two RF negative control sera. The anti-EBV VCA IgG decreased by averages of 21% in the RF positive RA sera and 27% in the RF negative control sera. In no RA case nor control did the serologic status of anti-EBV-VCA IgG change

from positive to negative (or vice versa). The simultaneous reduction in the antibody titer against a control antigen (varicella zoster) was exactly the same, 21% and 27%, respectively. By our data and the experience in the literature we are led to the conclusion that RF does not interfere with the anti-EBV-VCA IgG assay.

4. We also have preliminary data in RAA with EBNA-1. We have constructed the 443 unique overlapping octapeptides from EBNA-1 used to analyze the specificity of response in sera from patients with lupus, as described in our patent applications, but have used them to evaluate the fine specificity of the anti-EBNA-1 IgG antibody response in an RA patient and a normal control (Figure 1). There are 641 amino acids in the sequence, but some are repetitive and therefore were made only once. This approach has been applied in a number of other studies from our laboratory.

Figure 1 shows the binding of a rheumatoid factor positive RA patient serum (A) and a sex, race and age matched negative control (B) to the 443 unique overlapping octapeptides of EBNA-1. The RA patient mounts a very diversified response against EBNA-1. The normal control, on the other hand, has a much more limited response. Note the apparently identical responses binding peptides near peptide number 210 and 260 in both the normal and the RA patient. Meanwhile, the RA patient has anti-EBNA-1 antibodies against a number of peptides not bound by the normal. Among these are octapeptides numbered 244 to 347 (⇩) which contain RLPFG which is crossreactive with collagen.

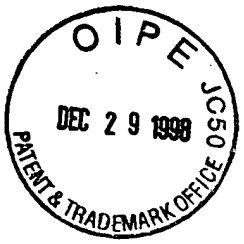
Many more of the EBNA-1 derived peptides are bound by the RA patient than are bound by the control. At the same time the RA patient binds all of those bound by the control. These results are, perhaps, consistent with the much higher frequency of precipitins against EBNA-1 in RA found in the precipitin studies in the literature relative to those results being immunoflorescence.

These data present the opportunity to define aspects of the fine specificity of the RA anti-EBV B cell response which are qualitatively unique to RA. Note that the RA patient binds all of the peptides bound by the matched control. In addition, there are a number of regions (octapeptides numbered 25 to 75, and those near 175, 275, 320, 345, 360, 385, 390, 410 and 420)

which are bound by the RA patient serum and not by the normal control. After collecting data from a number of such pairs and other inflammatory disease controls we could identify those relatively specific for RA. Interestingly, Octapeptides numbered 344 to 347 contain RLPFG which has shown to be immunologically crossreactive with collagen and is, therefore, a strong candidate for being a relatively RA specific anti-EBV response

5. The literature and our data as presented above leads us to suspect that the following model or scenario concerning RA is true. Because of genetic factors (e.g. HLA-DR4) some individuals have increased risk of becoming affected with RA. Some RA patients have an abortive infection of their synovium with EBV. These elements then are responsible for or predictive of the following: an association of EBV with RA (Table 6), humoral immune abnormalities in RA directed against EBV (Table 6), the relative absence of specific anti-EBV T cell activity in the peripheral blood (failure to suppress transformed B cell outgrowth) of RA patients, and the concentration of anti-EBV early antigen T cell activity in RA synovium of some patients.

6. The Examiner has requested data showing that one can prevent or alleviate symptoms of autoimmune disorders using our claimed compositions. This data in human is not currently available. However, studies have been conducted, as described in our application that show that certain peptide sequences present in EBV peptides can induce autoimmune disease. We have also conducted studies showing that we can induce tolerance to these same peptides, so that autoimmune disease is not induced.



7. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements are made with the knowledge that willful false statements are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: _____ _____

John B. Harley

CURRICULUM VITAE

John B. Harley, M.D., Ph.D.

Personal Data

Date of Birth: September 13, 1949

Married: Barbara West on August 8, 1972

Children: Andrew West Harley, September 5, 1979
Isaac Thomas West Harley, January 2, 1982

Education

1976	Ph.D.	University of Pennsylvania, Philadelphia, Pennsylvania (Biochemistry)
1974	M.D.	University of Pennsylvania, Philadelphia, Pennsylvania
1971	B.S.	Dickinson College, Carlisle, Pennsylvania (Physics and Chemistry)

Professional Experience

1982 - Present	James R. McEldowney Professor of Immunology and Professor of Medicine (1992 to present), Associate Professor (1986 to 1992), Assistant Professor (1982 to 1986), Department of Medicine, University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma
1982 - Present	Member (1998 to present) Associate Member (1989 to present), Affiliated Associate Member (1986 to 1989), Affiliated Assistant Member (1982 to 1986), Arthritis and Immunology Program, Oklahoma Medical Research Foundation, Oklahoma City, Oklahoma
1983 - Present	Adjunct Professor (1992 to present), Adjunct Associate Professor (1988 to 1992), Adjunct Assistant Professor (1983 to 1988), Department of Microbiology, University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma
1996 - Present	Adjunct Professor, Department of Pathology, University of Oklahoma Health Sciences Center, Oklahoma City, Oklahoma
1982 - Present	Staff Physician (1982, 1984 to 1987 and 1992 to present), Clinical Investigator (1987 to 1992), Immunology Section, Medical Service, Veterans Administration Medical Center, Oklahoma City, Oklahoma
1981 - 1982	Postdoctoral Fellow in Rheumatology, Arthritis Branch, National Institute of Arthritis, Diabetes and Digestive and Kidney Diseases, National Institutes of Health, Bethesda, Maryland

1979 - 1982	Clinical Associate, Laboratory of Immunoregulation, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland
1977 - 1979	Intern and Resident in Internal Medicine, Yale University, New Haven, Connecticut
1976 - 1977	Postdoctoral Fellow, Department of Tumor Immunology, Imperial Cancer Research Fund Laboratories, London, England
1975 - 1977	Postdoctoral Fellowship from the National Institute of Allergy and Infectious Diseases with Departments of Microbiology, Biochemistry and Biophysics, University of Pennsylvania, Philadelphia, Pennsylvania
1974	Assistantship in Physiology, University of Pennsylvania Philadelphia, Pennsylvania
1970	Co-Director, Halfway House, Dauphin County Unit, Harrisburg State Hospital, Harrisburg, Pennsylvania

Military Service

July 1, 1979 - June 30, 1982	Active Duty, Public Health Service: Senior Assistant Surgeon (03), July 1, 1979; Surgeon (04), February 1, 1980

Board Certification

1979	Diplomate of the American Board of Internal Medicine
1982	Diplomate of the American Board of Rheumatology
1983	Diplomate of the American Board of Allergy and Immunology

Scientific Recognition

Landis-Mohler Prize in Physics (1968)
A. J. Carnell Fellowship, Medicine (1972)
Edgar J. Kaufman Fellowship, Biochemistry (1973)
Balduin-Lucke Award in Medical Research (1974)
Arthritis Investigator Award, Arthritis Foundation (1985)
Young Investigator Award, National Institutes of Health (1985)
Arthritis Foundation Travel Award (1986)
Appointed by Governor George Nigh to the Oklahoma Health Research Committee (1986)
Alumni Research Scholar, University of Oklahoma College of Medicine (1987)
Clinical Investigator Award, Veterans Administration (1987)
Recognition of Outstanding Contribution, Faculty Senate, University of Oklahoma Health Sciences Center (1988)
Provost Research Award, University of Oklahoma Health Sciences Center (1988)
ASHI Scholar Award, American Society Histocompatibility and Immunogenetics (1989)

Prix de la Meilleuve Communication Scientifique, Premieres Journees Bretonnes D'Autoimmune (1990, shared with L. Jacobsson, B. Hansen, K. Hardgrave and R. Manthorpe)
Howard and Martha Holley Research Prize, American College of Rheumatology and the University of Alabama in Birmingham (1991)
James R. McEldowney Professorship in Immunology, University of Oklahoma (1992)
Wallace Graham Lecturer, University of Ottawa (1992)
Philip Hench Award, Association of Military Surgeons of the United States (1996)

Professional Societies

American Federation for Medical Research (1980)
American Rheumatism Association (1983)
Oklahoma Academy of Science (1983)
Oklahoma Rheumatism Society (1983)
American Association of Immunologists (1984)
American Society for Histocompatibility and Immunogenetics (1987)
Central Society for Clinical Investigation (1987)
Oklahoma Allergy Society (1988)
American Society for Clinical Investigation (1990)
American Association for the Advancement of Science (1991)
American Society for Human Genetics (1993)
Clinical Immunology Society (1995)

Institutional Duties

Fleming Scholar Committee, Oklahoma Medical Research Foundation, Chairman (1983-1986); Member (1983-present)
Electron Paramagnetic Resonance Facility Committee, Oklahoma Medical Research Foundation, Member (1985-1989)
Pharmacy and Therapeutics Committee, Oklahoma Memorial Hospital, Member (1983-1991); Chairman (1984-1989)
University Council on Faculty Awards and Honors, University of Oklahoma (1988-1991)
Oklahoma Medical Research Foundation Lecture Series Committee, Member (1989-1991)
MD/PhD Program, College of Medicine, University of Oklahoma, Director (1989-present), MD/PhD Advisory Committee (1989-present)
Department of Medicine Executive Committee, Member representing Associate Professors (1989-1991) and Professors (1993-1995)
Honorary Degree Screening Committee, University of Oklahoma, Member (1990-1993)
Center for Molecular Medicine, University of Oklahoma, Member (1991-)
Search Committee, Associate Chief of Staff for Research, Department of Veterans Affairs Medical Center, Member (1991-1992).
Search Committee for Gammill Chair in Polycystic Kidney Disease, Member (1996-1997)

Professional Service

American Federation of Clinical Research, Senator representing the University of Oklahoma (1983-1986)
Scientific Advisory Committee, Oklahoma Lupus Association, Member (1986-)

Rheumatology Abstract Review Committee, American Federation for Clinical Research, Member (1986)
National Subcommittee for Chapter Grant Review, Arthritis Foundation, Member (1985-1987).
Lupus Council, Arthritis Foundation, Member (1986-1990)
Oklahoma Health Research Committee, Member (1986-1995, Appointee of Governor George Nigh); Chairman (1986-1995)
Humoral Immunology Abstract Review Committee, American Rheumatism Association, Member (1987-1988)
Ad hoc Site-Visit Review Group, National Institute of Arthritis and Musculoskeletal and Skin Disease, Member (1987)
N.A.T.O. Collaborative Research Program, Collaborators on Complete Congenital Heart Block, Coordinator (1986-1988)
Scientific Review Committee, Presbyterian Health Foundation, Approved But Not Funded Program, Member (1988-1989)
Centers of Excellence Planning Committee, OCAST, Substitute Member (1988)
Two to Grown On, Executive Committee, Member (1988, Appointee of Governor Henry Bellmon)
By-Laws Committee for the Professional Practice Plan, Chairman (1988)
Systemic Lupus Erythematosus Etiology and Pathogenesis, Abstract Review Committee, American College of Rheumatology, Member (1989-1992)
Autoimmunity Minisymposium, Federation of the American Societies of Experimental Biology, American Association of Immunologists, Chairman (1990)
Editorial Board, Arthritis and Rheumatism (1990-1993)
Arthritis Research Council Special Site Visit Review Committee, National Institute for Arthritis and Musculoskeletal Diseases, Member (1990)
AFCR, ASCI, AAP National Meeting, Abstract Selection Committee, Chairman for Rheumatology (1991)
Editorial Board, Clinical and Experimental Rheumatology (1991-1994)
Program Specialist, Merit Review Board in Immunology, Research Services, U.S. Department of Veterans Affairs (1991-1994 and 1994-1997)
Reviewer's Reserve, National Institutes of Health, member (1992-1993)
General Medicine A Study Section, Division of Research Grants, National Institute of Health, ad hoc member (1992)
Specialized Centers of Research in Rheumatoid Arthritis Study Section, National Institute for Arthritis, Musculoskeletal and Skin Disease, Member (1992)
Experimental Immunology Study Section for Request for Applications "The effects of silicone on the immune response and in autoimmunity", Division of Research Grants, National Institutes of Health, Member (1993)
General Medicine A-2 Ad Hoc Review Section (AHR-M2), National Institutes of Health, Member (1993)
General Medicine A Study Section, Division of Research Grants, National Institutes of Health, Member (1993-1997)
Internal Administrative Advisor to "Sensory Integration Relevant to Cardiopulmonary Function" a Program Project proposal, Robert D. Foreman, Principal Investigator (1994)
Lupus Foundation of America, Medical Council, Member (1994-1996)
Clinical Sciences Special Emphasis Panel, National Institutes of Health, Member (1994)
Special Review Committee, National Institutes of Arthritis, Musculoskeletal and Skin Disease, Chairman (1995)

Oklahoma Center for the Advancement of Science and Technology (OCAST), Member of the Board of Directors (1995-present; Appointee of Governor Frank Keating); Vice Chairman (1995-1996 and 1996-1997)
American Association of Immunologists, Member of the Public Affairs Committee (1996-Present)
Ad hoc Technical Evaluation Group for RFP NIH-NIAMS-96-001, "Gene Therapy for Rheumatic and Skin Diseases", National Institute of Arthritis, Musculoskeletal and Skin Diseases, Chairman (1996)
University of Michigan Lupus SCOR, Member, Scientific and Administrative Advisory Committee (1997 - present)
NIAID Task Force on Immunology, Member (1997-1998)
Clinical Infrastructure Task Force, S.L.E. Foundation (1998-present)

Attending Physician

Oklahoma Memorial Hospital, Oklahoma City
U.S. Department of Veterans Affairs Medical Center, Oklahoma City
Oklahoma Children's Memorial Hospital, Oklahoma City

Supervision of Students and Postdoctoral Fellows
Ph.D. Candidates

Mark J. Mamula	Ph.D.	1986	The role of the Ro/SSA ribonucleoprotein
Microbiology			as an immunogen: A study of the antigen binding properties
Myra O. Rosario	Ph.D.	1987	Studies on the immunology of the human
Microbiology			ribonucleoprotein autoantigen Ro/SSA
Kimberley K. Gaither	Ph.D.	1987	Anti-Ro/SSA in normal sera and its role
Microbiology			in the pathogenesis of neonatal lupus syndrome (R.A. Patnode Award, Sigma Xi Award)
Charles A. O'Brien	Ph.D.	1990	A subset of hY RNAs are associated with
Microbiology			erythrocyte Ro RNPs and the sequence of hY4 RNA (Sigma Xi Award)
Judith A. James	Ph.D.	1993	Sequential fine specificity of Sm and nRNP associated proteins
A. Darise Farris	Ph.D.	1995	Phylogenetic analysis of Ro ribonucleoprotein associated small RNAs
Kathy L. Moser	Ph.D.	1995	Genetic linkage analysis of chromosome 1 marker loci to systemic lupus erythematosus and anti-nuclear antibodies.
Melissa Arbuckle			Dissertation research underway

Summer Student Research Scholars

Michael D. Rader	1983	Sir Alexander Fleming Scholar
Andrea L. Sestak	1984	Sir Alexander Fleming Scholar
Ann J. Althizer	1985	Sir Alexander Fleming Scholar
E. Michele Southard	1986	Sir Alexander Fleming Scholar
Dedra Butler	1987	Sir Alexander Fleming Scholar
Julie Cleek	1988	OMRF Scholar

Judith Ann James	1988	Sir Alexander Fleming Scholar
Grace Yin Jenq	1989	Sir Alexander Fleming Scholar
Cy Anderson	1989	SURE Program Scholar
Holly Moreu	1990	Sir Alexander Fleming Scholar
David Stec	1990	SURE Program Scholar
Juliet von Egmond	1991	SURE Program Scholar
Kennith Layton	1991	Sir Alexander Fleming Scholar
W. Cody Holloway	1992	Sir Alexander Fleming Scholar
Tina Grover	1992	Presbyterian Harris Summer Fellow
Lee Warren	1992	Presbyterian Harris Summer Fellow
Melissa Arbuckle	1993	SURE Program Scholar
Monica S. Reid	1993	Sir Alexander Fleming Scholar
Rivka Galchen	1994	Sir Alexander Fleming Scholar
Robert Clay Musser	1994	Sir Alexander Fleming Scholar
Lydia D. Nightingale	1995	Sir Alexander Fleming Scholar
Micah T. McClain	1995	Sir Alexander Fleming Scholar
Audrey Brumback	1995, 1996	Summer Student
Rivka Galchen	1995	Summer Student
Connie Zhai	1995	Summer Student
Lydia Nightingale	1996, 1997, 1998	Summer Student
Teresa Hall	1996	Summer Student
Mark Goodman	1996	Summer Student
Jared Ning	1996, 1997	Summer Student
Jenifer Hahn	1996	Summer Student
Micah Mc Clain	1996	Summer Student
David Williams	1996	Summer Student
Alyssa Shilling	1997	Sir Alexander Fleming Scholar
Alan Lee	1997	Summer Student
Nelson Fong	1997, 1998	Summer Student
Anup Shetty	1998	Sir Alexander Flemming Scholar

Postdoctoral Fellows, Rheumatology Clinical Fellows and Research Scientists

Owen F. Fox, Ph.D.	1983-1987
Larry G. Willis, M.D.	1985-1986
Dan Axthelm, M.D.	1986-1987
Atsushi Fujisaku, M.D., Ph.D.	1986-1989
Kimberley K. Gaither, Ph.D.	1987-1988
W. Daryl Dickey, M.D., Ph.D.	1988-1991
R. Hal Scofield, M.D.	1988-1991
Bettina Mues, M.D., Ph.D.	1989-1990
Jose Troncoso, M.D.	1989-1991
Shu-Cai Huang, Ph.D.	1991-1993
Timothy Shaver, M.D.	1993-1994
Sangita Deveshwar, M.D.	1993-1995
Judith A. James, M.D., Ph.D.	1993-1995
Kenneth M. Kaufman, Ph.D.	1994-present
A. Darise Farris, Ph.D.	1995-1996

Kathy L. Moser, Ph.D.	1995-present	
Iman Ali, M.D.	1997-present	
Andrea Sestak, M.D., Ph.D.	1997-present	

Faculty Support

Shaili Deveshwar, M.D.	1995-1996	Assistant Professor Department of Pediatrics University of Oklahoma
Kenneth M. Kaufman, Ph.D.	1994-present	Research Assistant Professor Department of Medicine University of Oklahoma
Judith A. James, M.D., Ph.D.	1995-present	Research Assistant Professor Department of Medicine University of Oklahoma
Barbara R. Neas, Ph.D.	1991-present	Assistant Professor Department of Biostatistics and Epidemiology University of Oklahoma
R. Hal Scofield, M.D.	1991-present	Assistant Professor Department of Medicine University of Oklahoma
	1991-present	Associate Member (1992-present), Assistant Member (1991-1992), Oklahoma Medical Research Foundation

Sabbatical and Visiting Scientists

Angela Horsfall, Ph.D.	1989-1990	Senior Scientist; Kennedy Institute for Rheumatology, London
Fanny Ebling, Ph.D.	1991	Associate Professor; Department of Medicine, University of California, Los Angeles
Jacob Karsh, M.D.	1992	Associate Professor; Department of Medicine, University of Ottawa, Ontario
Thomas Gordon, M.D.	1995-1996	Associate Professor; Department of Medicine, Flinders University Adelaide, Australia

Ramnath Misra, M.D.	1997	WHO Fellow Additional Professor Department of Clinical Immunology Sanjoy Gandi Postgraduate Institute of the Medical Sciences Lucknow, India

Research Support

Active Research Support

National Institutes of Health T32 AI07364-01 to 05
"Molecular Pathogenesis Training Program"
Principal Investigator: John Iandolo, Ph.D.
Training Personnel: J.B. Harley
2% time and effort
2/1/98 to 1/31/03: $111,568 total direct costs
2/1/98 to 1/31/99: $ 69,304 direct costs

National Institutes of Health T32 AR07580
"Immunological Training in Rheumatology and Dermatology"
Principal Investigator: M. Reichlin
Training Personnel: J.B. Harley
1% time and effort
7/1/94 to 6/30/99: $ 328,900 total direct costs
7/1/98 to 6/30/99: $ 65,520 direct costs

U.S. Department of Veterans Affairs, Merit Review Program, CC103
"Anti-Ro Autoantibody"
Principal Investigator: J.B. Harley
10% time and effort
10/1/94 - 9/30/99: $465,500 total direct costs
10/1/98 - 9/30/99: $ 93,100 direct costs

National Institutes of Health, Contract No. N01-AR-5-2221
"Lupus Multiplex Registry and Repository"
Principal Investigator: J.B. Harley
up to 20% time and effort
9/30/95 - 9/29/01: $3,641,507 total costs
9/30/98 - 9/29/99: $ 674,714 direct costs

National Institutes of Health K08 AR01981-01 to 05
"Genetic Analysis of Lupus Autoimmunity"
Principal Investigator: Judith A. James, M.D., Ph.D.
Mentor: J.B. Harley
9/30/96 - 8/31/01: $378,722 total direct costs
9/30/98 - 8/31/99: $ 71,460 direct costs

National Institute of Health R01 AI31584-04
"A Possible Infectious Etiology for Lupus"
Principal Investigator: J.B. Harley
4% time and effort
9/1/97 - 8/31/02: $864,935 total direct costs
9/1/97 - 8/31/98: $168,833 first year direct costs

National Institute of Health P50 AR45231-01
"Specialized Center of Research in Systemic Lupus Erythematosus"
Projects #2. "Multiplex and Simplex Pedigrees in the Genetics of Lupus"
Principal Investigator: Robert P. Kimberly, M.D.
Project #2 Investigator: J.B. Harley
20% time and effort
7/1/98 - 6/30/02: $600,000 total direct costs
7/1/98 - 6/30/99: $150,000 direct costs

Pending Research Support

National Institutes of Health RO1 AR42474-06 to 10
"Epstein-Barr Virus in Lupus"
Principal Investigator: J.B. Harley
2/1/99 - 1/31/04: $1,006,331 total requested direct costs
2/1/99 - 1/31/00: $185,796 requested direct costs

National Institutes of Health RO1 AR42460-06 to 10
"Genetic Association with Lupus in American Blacks"
Principal Investigator: J.B. Harley
4/1/99 - 3/31/04: $2,026,214
4/1/99 - 3/31/00: $351,272

National Institutes of Health R03
"Epistasis With A Gene Near D1s229 In Lupus"
Principal Investigator: J.B. Harley
12/1/98 - 11/30/02: $150,000 total requested direct costs
12/1/98 - 11/30/99: $ 50,000 requested direct costs

Arthritis Foundation
"Epistasis with D1s229 in Lupus"
Principal Investigator: J.B. Harley
7/1/99 - 6/30/04: $416,665 total requested direct costs
7/1/99 - 6/30/00: $ 83,333 requested direct costs

U.S. Department of Veterans Affairs
"Research Enhancement Award"
Principal Investigator: J.B. Harley
1/1/99 - 6/30/99: $ 40,000 direct costs

Previous Research Support

U.S. Department of Veterans Affairs
"VAMC Genotyping and Sequencing Center"
Principal Investigator: J.B. Harley
7/20/98 - 9/30/98: 465,760

U.S. Department of Veterans Affairs
"Medical Research Service Equipment Request"
Principal Investigator: J.B. Harley
7/1/98 - 9/30/98: $67,000

National Institutes of Health R01 AI24717-07 to 11
"Genetic Linkage in Lupus"
Principal Investigator: J.B. Harley
9/30/93 to 8/31/98: $537,746

National Institutes of Health R01 AR42474
RFA AR-93-005 "Research on Causal Mechanisms in Systemic Lupus Erythematosus"
"Peptides Induce Lupus Autoimmunity"
Principal Investigator: J.B. Harley
9/30/93 to 8/31/98: $547,843

National Institutues of Health
"Genetic Linkage in Lupus Research Supplement for a Minority Postdoctoral Trainee"
Principal Investigator: J.B. Harley
10/1/95 - 8/31/98: $117,630

National Institute of Health T32 GM08237-08 to 10
"Septic Shock And Tissue Injury"
Principal Investigator: Gary T. Kinasewitz, M.D.
Training Personnel: J.B. Harley
7/1/96 to 6/30/97 $69,100
7/1/97 to 6/30/98 $72,000 total direct costs

National Institutes of Health R01 AR42460
RFA AR-93-006 "Systemic Lupus in Women and Minorities"
"A Genetic Association with Lupus in American Blacks"
Principal Investigator: J.B. Harley
9/30/93 to 5/31/98: $504,504 total direct costs

National Institutes of Health T32 AI07364-01 to 05
"Molecular Pathogenesis Training Program"
Principal Investigator: Joseph J. Ferretti, Ph.D.
Training Personnel: J.B. Harley
2/1/93 to 1/31/98: $226,994

National Institutes of Health K11 AR01844
Physician Scientist Award
"Origin of Anti-Ro/SSA Antibody"

Principal Investigator: Robert Hal Scofield, M.D.
Sponsor: J.B. Harley
3/1/92 to 2/28/97: $335,000

National Institutes of Health R01 AR42474-S1
Research Supplement for Minority Investigators
"Peptides Induce Lupus Autoimmunity"
Principal Investigator: J.B. Harley
Co-Principal Investigator: J.A. James
2/1/95 to 1/31/97: $134,610

National Institutes of Health F31 GM14841
"MARC Predoctoral Fellowship"
Judith A. James, Fellowship Recipient
John B. Harley M.D., Ph.D., Sponsor
10/1/91 to 9/30/96: $81,800

National Institutes of Health R01 AI31584
"Y RNA Sequences and Ro RNP Function"
Principal Investigator: J.B. Harley
7/1/91 to 6/30/96: $155,655

U.S. Department of Veterans Affairs, Merit Review Program CC103
"Human Anti-Ro/SSA Producing Xenografts"
Principal Investigator: J.B. Harley
10/1/91 to 9/30/94: $173,794

National Institutes of Health, Program Project, P01 AI21568-06 to 08
"Autoantibodies in SLE and Polymyositis"
Program Director: Morris Reichlin, M.D.
9/1/90 to 6/30/94: $1,253,561 total approved direct costs

Core C
"Experimental Design and Statistical Analysis"
Principal Investigator: J.B. Harley
9/1/90 to 7/31/94: $39,599
Project 3
"Autoantigenicity of Sm and nRNP"
Principal Investigator: J.B. Harley
9/1/90 to 7/31/94: $221,829

Presbyterian Health Foundation
MD/PhD Program
Principal Investigator: J.B. Harley
11/1/92 to 10/30/93: $104,000 approved direct costs

National Institute of Health, R01 AI24717-04 to 06
"HLA-DQ Gene Complementation in Lupus"
Principal Investigator: J.B. Harley

4/1/90 to 8/31/93: $241,338

National Institutes of Health, T32 GM08237
"Septic Shock and Tissue Injury"
Principal Investigator: Lerner Hinshaw, Ph.D.
Supporting Investigator: J.B. Harley
7/1/88 to 6/30/93: $190,242

National Institutes of Health, R01 AR39577-01 to 03
"Antiidiotypes in Congenital Heart Block and Neonatal Lupus"
Principal Investigator: J.B. Harley
2/1/89 to 3/31/93: $239,000

Veterans Administration Clinical Investigator Award (CC108)
"HLA Gene Complementation in Systemic Lupus"
Principal Investigator: J.B. Harley
7/1/87 to 3/31/93: $585,000

Arthritis Foundation, Oklahoma City Chapter
"Mouse and Rabbit Y RNA Sequences"
Principal Investigator: J.B. Harley
11/1/90 to 10/31/91: $9,260

OCAST Equipment Contract
"Autoimmune Responses in Polymyositis"
Principal Investigator: M. Reichlin
Co-Investigator: J.B. Harley
9/1/89 to 8/30/90: $26,177

March of Dimes Birth Defects Foundation (1-1109)
"Immunopathogenesis of Congenital Heart Block"
Principal Investigator: J.B. Harley
7/1/88 to 6/30/90: $60,000

National Institutes of Health, R01 AI24717
"HLA Gene Complementation in Primary Sjögren's and Lupus"
Principal Investigator: J.B. Harley
Co-Principal Investigator: M. Barton Frank, Ph.D.
4/1/87 to 6/30/90: $244,537

Arthritis Foundation - Arthritis Investigator Award
"Autoimmune Epitopes of Ro/SSA I."
Principal Investigator: J.B. Harley
7/1/85 to 6/30/88: $108,000

College of Medicine Alumni Research Fund
"Autoimmune Epitopes of Ro/SSA II."
Principal Investigator: J.B. Harley
7/01/87 to 1/31/89: $18,296

National Institutes of Health AM34159
"Immunology of the Autoantigen Ro/SSA and La/SSB"
Principal Investigator: J.B. Harley
4/1/85 to 3/31/88: $ 150,000

National Institutes of Health, AM 34159
"Immunology of the Autoantigens Ro/SSA and La/SSB"
Principal Investigator: J.B. Harley
4/1/85 to 3/30/88: $107,500

NATO Scientific Affairs Division, RG 86/0564
Collaborative Research Grant Program RG.86/0564
"Autoantibodies in Complete Congenital Heart Block"
Project Coordinator: J.B. Harley
3/86 to 12/87: $5,000

Veterans Administration Medical Research Service,
CC 103 (Merit Review)
"RNA-Protein in Autoimmune Diseases"
Principal Investigator: J.B. Harley
1/1/86 to 12/31/87: $95,400

March of Dimes Birth Defects Foundation,
Basil O'Connor Starter Research Grant
"Anti-Ro/SSA and Congenital Complete Heart Block"
Principal Investigator: J.B. Harley
9/1/85 to 8/31/87: $50,000

National Institutes of Health, R01 DE 06740
"Human Antibody Responsiveness and Dental Caries"
Principal Investigator: Martin Levine, Ph.D.
Co-Investigator: J.B. Harley
7/1/84 to 6/30/87: $207,445

Veterans Administration Medical Research Service, CC 103 (RAG)
"Autoantigen Recovery in Autoimmune Disease"
Principal Investigator: J.B. Harley
1/1/85 to 12/31/85: $25,000

Oklahoma Chapter Arthritis Foundation
"Monoclonal Antibodies Against Ro/SSA"
Principal Investigator: J.B. Harley
7/1/84 to 6/30/85: $5,500

Oklahoma Lupus Association, Inc.
"Anti-Ro/SSA Autoantibodies in Normal Individuals"
Principal Investigator: J.B. Harley
6/1/84 to 5/31/85: $3,500

Oklahoma Chapter, Arthritis Foundation
"Does Epstein-Barr Virus Cause Rheumatoid Arthritis?"
Principal Investigator: J.B. Harley
7/1/82 to 6/30/83: $3,500

Oklahoma Chapter, Arthritis Foundation
"Immunohistochemical Identification of the Isoenzymes of G6PD"
Principal Investigator: J.B. Harley
7/1/82 to 6/30/83: $8,500

National Institutes of Health, AI 05186
"Phagocytosis and Lipid Acyl Chain Composition in *Escherichia Coli*"
Principal Investigator: J.B. Harley
7/1/75 to 7/1/77: $26,000

Patents

U.S. Patent No. 4,784,942 entitled "Monoclonal antibodies against autoimmune RNA proteins," issued November 15, 1988. Inventor, J.B. Harley

U.S. Patent No. 5,264,351 entitled "Monoclonal antibodies against autoimmune RNA proteins," issued November 23, 1993. Inventor, J.B. Harley

U.S. Patent No. 5,637,454 entitled "Assays and treatments for autoimmune diseases." Issued June 10, 1997. Inventor, J.B. Harley [OMRF 114]

U.S. Patent No. 5,719,064 entitled "Peptide diagnostics and therapeutics for spondyloarthropathies". Issued February 17, 1998. Inventors R.H. Scofield and J.B. Harley.

Continuation in Part U.S. Patent applied for "Assays and treatments for autoimmune diseases." Provisional U.S. Serial Number: 08/335,198, Unofficial Filing Date April 13, 1992. Inventor, J.B. Harley [OMRF 116 CIP (1)], Notice of allowance issued in October 24, 1996 for claims 1-8, 10, 64-65.

Continuation in Part U.S. Patent applied for "Methods and reagents for diagnosis of autoantibodies." Provisional U.S. Serial Number: 07/867,819, Unofficial Filing Date June 22, 1992. Inventor, J.B. Harley [OMRF 114 CIP (2)]

U.S. Patent applied for "Peptide diagnostics and therapeutics for spondyloarthropathies." Provisional U.S. Serial Number: 07/944,143, Unofficial Filing Date August 31, 1992. Inventors, R. Hal Scofield and J.B. Harley [OMRF 138] Patent issued in U.S.A.

Continuation in Part U.S. Patent applied for "Peptide and induction of autoimmunity and clinical symptomology." Provisional U.S. Serial Number 08/160,604 Unofficial Filing Date, November 30, 1993. Inventors, J.B. Harley, J.A. James and R.H. Scofield [OMRF 114 CIP (3)] *[1]Applications pending in Europe (93910594.6), Japan (5-518573), Australia (41028193) and Canada (2,117,904).

U.S. Patent applied for "Diagnostics and therapy of Epstein-Barr virus in autoimmune disorders". Provisional U.S. Serial Number pending. Inventors, J.B. Harley and J.A. James [OMRF 161] Unofficial filing date January 13, 1997.

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GenBank Sequence Database Submissions

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2. O'Brien, C.A. and J.B. Harley. H. Sapien (clones B7, B8 and F2) hY4 Ro RNA pseudogenes. Dec. 14, 1992. Accession Numbers: M77130-M77132; Locus: HUMHY4ROA, HUMHY4ROB and HUMHY4ROC.

3. Farris, A.D. and J.B. Harley. Iguana small cytoplasmic RNA (Y3 and Y4). Jan. 11, 1994, Accession Numbers: L27530-L27537; Loci: IGUY3A, IGUY3B, IGUY3C, IGUY3D, IGUY4A, IGUY4B, IGUY4C, IGUY4D. Corrections submitted August 11, 1994.

Publications

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Revisions and update made 10/19/98

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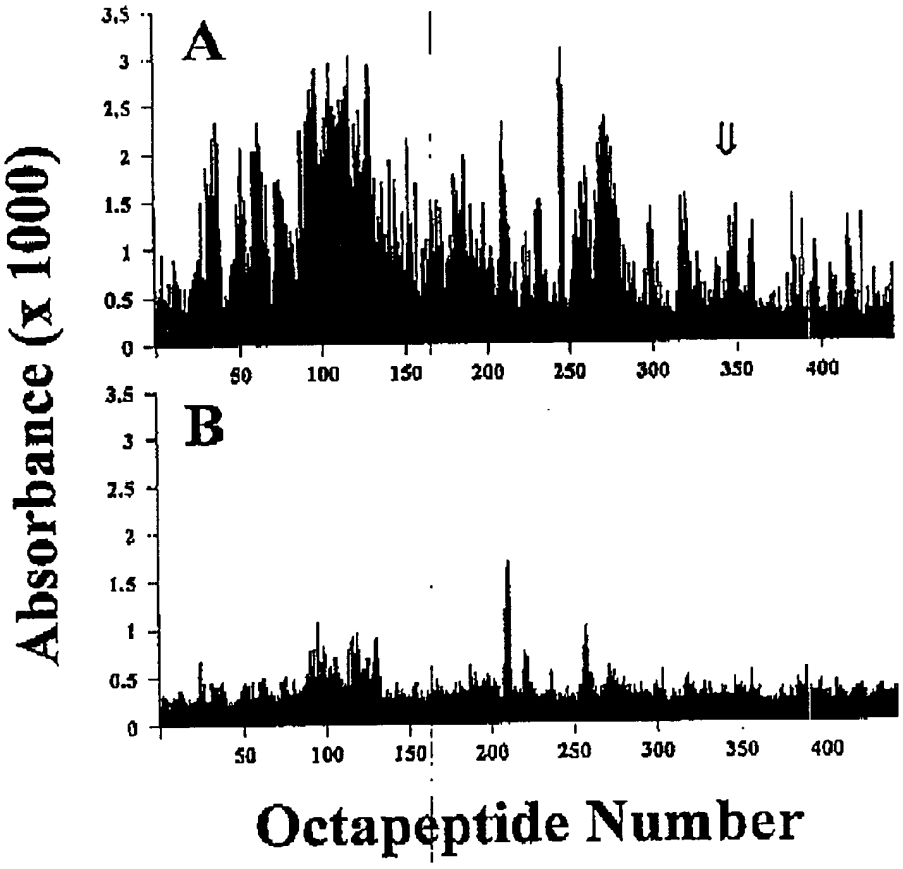

Figure 1. Binding of a rheumatoid factor positive RA patient serum (A) and a sex, race and age matched negative control (B) to the 443 unique overlapping octapeptides of EBNA-1. The RA patient mounts a very diversified response against EBNA-1. The normal control, on the other hand, has a much more limited response. Note the apparently identical responses binding peptides near peptide number 210 and 260 in both the normal and the RA patient. Meanwhile, the RA patient has anti-EBNA-1 antibodies against a number of peptides not bound by the normal. Among these are octapeptides numbered 344 to 347 (⇓) which contain RLPFG which is crossreactive with collagen (122).

D. Experimental Design and Methods. The literature and our preliminary data as presented above leads us to suspect that the following model or scenario concerning RA is true. Because of genetic factors (e.g. HLA-DR4) some individuals have increased risk of becoming affected with RA. Some RA patients have an abortive infection of their synovium with EBV (2). These elements then are responsible for or predictive of the following: an association of EBV with RA (Table 6), humoral immune abnormalities in RA directed against EBV (Tables 1-6), the relative absence of specific anti-EBV T cell activity in the peripheral blood (failur to suppress transformed B cell outgrowth) of RA patients, and the concentration of anti-EBV early antigen T cell activity in RA synovium of some patients (43,62). The specific aims address this model of EBV in RA by seeking to develop the predicted observations.